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TVT-ABBREVO: efficacy and two years follow-up for the treatment of stress urinary incontinence

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Summary

Purpose: to assess the effectiveness of inside-out TVT-ABBREVO in the surgical treatment of female stress urinary incontinence (SUI) with mean two-year follow-up. **Materials and methods:** Fifty-six women underwent surgery for moderate-severe SUI. The technology used was the TVT-ABBREVO inside-out. Each woman at 12 and 24 months underwent postoperative evaluation by means of urodynamics, Q-tip test, CST, transperineal ultrasonography, and administration of "King's Health Questionnaire" (KHQ). **Results:** The mean age of the women was 57.03 ± 11.1 years (range 42-75). Postoperative urodynamics (12 months follow-up) resulted to be normal in 43/56 patients (76.79%), in 10/56 (17.86%) cases resulted in a considerable improvement of the symptomatology, and only 1/56 (1.78%) case had de novo overactive bladder (OAB), in 2/56 (3.57%) symptomatology unchanged. After administration of the KHQ 43/56 cases (76.79%) had resolution of the symptomatology, 10/56 cases (17.86%) improvement of the symptomatology, and no change in 3/56 cases (5.36%). **Conclusion:** In the authors' experience, the TVT-ABBREVO resulted technically simple. The TVT-ABBREVO procedure provides high objective and subjective long term efficacy, a clinically meaningful improvement in patient quality of life, and an excellent safety profile.

Key words: Stress urinary incontinence (SUI); TVT-Abbrevio.

Introduction

Stress urinary incontinence (SUI) is an important public health problem and affects up to 20% of women worldwide [1].

Combination therapy with estriol plus pelvic floor rehabilitation was effective for treatment of symptoms of urogenital aging in postmenopausal women, such as urogenital atrophy, frequency of urinary tract infections, as well as the symptoms and signs of SUI [2-3]. Recently, the present authors have demonstrated that triple therapy should be considered the first line-treatment for mild SUI in postmenopausal women [4].

Several surgical procedures, both vaginal and abdominal, have been proposed over the years for treating SUI. Nowadays midurethral slings, such as retropubic tension-free vaginal tape (TVT) [5], and the transvaginal tension-free vaginal tape obturator, or transobturator tape (TVT-O, TOT) have become the gold standard to treat severe SUI [6].

The inside-out TVT-Obturator (TVT-O) system was introduced with the objective to abstain the retropubic space in order to avoid the risk of lower urinary tract injury, while providing minimal vaginal and paravaginal tissue dissection and reproducibility of the tape's insertion [7]. A meta-analysis of randomized controlled trial has demonstrated equivalent SUI cure rates after retropubic and transobturator tape procedures (approximately 85% to 90% at three years postoperatively); however, the transobturator approach is associated with less voiding dysfunction,

blood loss, bladder perforation, and shorter operating time [8].

The aim of this study was to assess the efficacy and follow-up of women undergoing TVT-O procedure for SUI. The authors used the TVT-ABBREVO, a new modified TVT-O procedure [9].

Materials and Methods

The TVT-ABBREVO is different from its original counterpart because in this new technique the tape length is shortened to 12 cm without any change in tape's characteristics (macroporous, monofilament polypropylene mesh).

Short description of the surgical technique

A urethral catheter was inserted and the bladder emptied. Using Allis clamps for traction, the vagina was incised with scalpel beginning at one cm proximal to the urethral meatus. Initial dissection was carried out with a cold knife blade and further dissection is done by a gentle "push-spread" technique for approximately three cm with fine-pointed, curved Metzenbaum scissors directed toward the ischiopubic ramus in a 45° angle in relation to the coronal plane. Dissection was performed before perforating the obturator membrane, which usually offers more resistance to perforation than the obturator internus muscle. Then a guide was inserted and the helical passer was the sole instrument to perforate the obturator membrane. The TVT-ABBREVO technique has been previously described in detail [9].

Inclusion criteria

- age > 40 < 85 years;
- SUI clinically and urodynamically demonstrated;
- Positive stress test;
- Maximum cystometric capacity ≥ 300 ml.

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Table 1. — Characteristics of patients.

Demographics	Mean ± SD (%)
Age	57.03 ± 11.1
Parity	2.1 ± 1.1
BMI	28.2 ± 3.5
Previous hysterectomy	7/56 (12.5)

Exclusion criteria:

- postvoid residual (PVR) ≥ 100 ml;
- detrusor overactivity or acontractility;
- contraindication to anesthesia;
- neurogenic bladder;
- active urinary or vaginal infection;
- pelvic organ prolapse (POP) requiring surgical correction (symptomatic or grade ≥ 3);

Follow-up and quality of life were assessed using the validated King's Health Questionnaire (KHQ) for SUI [10].

Institutional Review Board approved the study

At the Gynecologic and Obstetric Clinic of Sassari University, 56 patients underwent TVT-Abbrevio procedure to treat moderate-severe SUI. Of the 56 patients, seven reported a history of major gynecological surgery (abdominal hysterectomy).

Before surgery adequate written informed consent was provided to the patients, and all women underwent routine preoperative examinations, urodynamics, urogynecologic examination, and transvaginal ultrasound.

Preoperative evaluation included:

- remote and recent medical history;
- clinical evaluation and analysis of the voiding diary completed by the patient at home for three days;
- urinalysis and urine culture;
- complete urodynamic examination;
- Q-tip test;
- cough stress test (CST).

Postoperative follow-up (mean two years, from six months to three years). The patients were visited at 12, 24, and 36 months after surgery.

The following investigations (12 months postoperatively) were performed:

- clinical assessment;
- complete urodynamic examination;
- Q-tip test;
- cough stress-test (CST);
- transvaginal ultrasound to assess the correct positioning of the mesh.

Objective cure was defined as the absence of urine leakage during the CST. Subjective cure was established when patients responded "never" in the question: "does urine leak when you are physically active, exert yourself, cough, or sneeze".

Quality of life improvement was defined by a decrease in KHQ domain scores. The minimal important clinical difference (the smallest change in score that patients perceived as good) was set at – 5 points for each KHQ domain.

Statistical analysis

Data are presented as means ± standard deviation (SD), medians, or percentages for normally and non-normally distributed continuous variables or categorical variables, respectively. Comparison for continuous variables before and after surgery results were done using the t test for paired data or Wilcoxon signed-rank test.

Table 2. — Domains covered by the King's Health Questionnaire.

Domain	Preoperative	Postoperative	Difference	p
General health	32.73 ± 18.21	22.84 ± 16.31	- 9.89	< 0.05
Incontinence impact	58.72 ± 23.32	24.68 ± 21.27	- 34.04	< 0.05
Role limitations	38.72 ± 18.41	13.15 ± 10.31	- 25.57	< 0.05
Physical limitations	35.64 ± 36.18	10.16 ± 09.53	- 24.88	< 0.05
Social limitations	23.71 ± 16.67	06.13 ± 05.71	- 17.58	< 0.05
Personal relationship	18.24 ± 09.84	05.23 ± 08.35	- 13.01	< 0.05
Emotions	38.13 ± 16.21	12.25 ± 11.37	- 25.88	< 0.05
Sleep and energy	26.15 ± 09.61	11.07 ± 10.39	- 15.08	< 0.05
Severity measures	33.24 ± 17.21	15.75 ± 11.31	- 17.49	< 0.05

Table 3. — Subjective cure rate.

Year/ case	Cured (%)	Improved (%)	Failed (%)
2010: 10	7/10 (70)	1/10 (10)	2/10 (20)
2011: 12	9/12 (75)	3/12 (25)	-
2012: 17	13/17 (76.47)	4/17 (23.53)	-
2013: 17	14/17 (82.35)	2/17 (11.76)	1/17 (5.89)
Total: 56	43/56 (76.79)	10 (17.86)	3 (5.36)

Results

Table 1 shows demographic characteristics of the study population. The age of patients ranged from 48 to 71 years (mean age 57.03 ± 11.1 years).

The mean operative time (from induction of anesthesia until the last suture) was 20 minutes, and all patients were subjected to general anesthesia. No major perioperative complications, such as bladder perforations, vessel injuries and obturator hematomas occurred. The Foley catheter was removed on the day following the intervention, inviting patients to urinate spontaneously. The hospital stay ranged from three to five days (mean three days).

Postoperative urodynamics (12 months follow-up) resulted to be normal in 43/56 patients (76.79 %), in 10/56 (17.86 %) cases resulted in a considerable improvement of the symptomatology, only 1/56 (1.78%) case had de novo overactive bladder (OAB), in 2/56 (3.57 %) unchanged symptomatology. The Q- tip test was normal (< 30°) and the CST was negative in all patients after surgery. Transperineal ultrasonography demonstrated normal positioning of the sling in all patients. After administration of the "King's Health Questionnaire" 43/56 cases (76.79 %) had resolution of the symptomatology, 10/56 cases (17.86%) improvement of the symptomatology, and no change in 3/56 cases (5.36 %). KHQ data analysis showed a statistically significant improvement in all domains (Table 2). Indeed, with regards to clinically relevant improvement, the difference between mean postoperative and preoperative values was over the minimal important clinical difference (the smallest change in score that patients perceived as beneficial) (Table 3).

At follow-up visit, no cases of vaginal erosions were reported. No patients reported persistent groin pain at long-term follow-up.

Discussion

The introduction of prosthetic materials “tension-free” at the level of the middle urethra led to a breakthrough in the surgical treatment of SUI. In particular, Ulmsten *et al.* and Petros *et al.* [11, 12] introduced the hypothesis of “tension-free” for the treatment of incontinence, based on clinical and experimental studies that demonstrated a more physiological mechanism of urethral closure under stress. The existing literature reveals how the technique of Ulmsten *et al.* had a high success rate for the treatment of SUI, quantifiable around 90% [5].

Afterwards, in order to avoid complications such as bladder and / or vascular injuries by the needle through the vascular tissues in the path between the suprapubic region and the periurethral, Delorme *et al.* [13] introduced the transobturator approach for the treatment of SUI. It is an exclusively perineal surgery that provides a natural support to the urethra by means of a cable positioning innovative through the obturator foramen and not the space of Retzius that could carry the risk of vascular lesions. The widespread use of this method, in addition to the reduction of complications, is mainly due to safety and the speed of execution [13].

In the present authors' experience, the positioning of TVT-ABBREVO was technically simple and very easy to position the tape lying flat under the urethra, reducing the risk of urine retention.

The present study included a sample of 56 patients aged between 42 and 75 years (mean 57.03 ± 11.1), undergoing TVT-ABBREVO from 2010 to 2013. In the postoperative period, a questionnaire was administered [10]. The results obtained by the administration of this questionnaire showed that 43/56 (76.79%) were cured; 10/56 (17.86%) cases showed a significant improvement in symptoms with an overall improvement in quality of life. Only 3/56 (5.36%) cases showed no improvement.

The present study showed a success rate of 94.64% (considering the total resolved cases and cases with marked improvement) and only in 5.36% of patients the problem of SUI was unresolved. Besides these encouraging data, the authors reported the absence of vascular complications such as bladder or bowel perforation, and episodes of retention.

In conclusion, the results of the present study proved very encouraging to date, given the level of satisfaction of

patients treated with this minimally invasive technique and the great results of the objective, linked to a recovery of a real functional well-being.

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